NCT02775071

Psychopathology, Disordered Eating, and Impulsivity as Predictors of Outcomes of Bariatric Surgery

October 8, 2018

IRB Protocol and Analysis Plan

Continuing Review

Basic Info

Confirmation Number:	**chejjgfb**
Protocol Number:	**823735**
Created By:	**ALLISON, KELLY C**
Principal Investigator:	**ALLISON, KELLY C**
Protocol Title:	**Psychopathology, Disordered Eating, and Impulsivity as Predictors of Outcomes of Bariatric Surgery**
Short Title:	**Psychosocial and Behavioral Aspects of Bariatric Surgery**
Protocol Description:	**This study evaluates the relationship between psychopathology, disordered eating, and impulsivity (through clinical interview, self-report measures, and objective testing) on changes in weight and psychosocial status for 2 years after bariatric surgery. Bariatric surgery patients (n=300) will complete assessments, including computer tasks, surveys, waist circumference, height/weight measurement, and urine drug screen before surgery and at 6, 12, and 24 months post surgery.**
Submission Type:	**Social and Biological Sciences**
Application Type:	**FULL**

PennERA Protocol Status

Approved

Level of IRB Review Required

Expedited Review

The following documents are currently attached to this item:

There are no documents attached for this item.

Summary of protocol modifications approved since last continuing review
Please provide a description of changes which have been reviewed and approved by the IRB since the last continuing review.

Subject Enrollment

Target subject enrollment at Penn

0

Target enrollment at other centers (multi-center study)

0

Number of subjects enrolled at Penn since the study was initiated

0

Actual enrollment at participating centers

0

Number of subjects enrolled at Penn since the last continuing review

Total number of subjects who provided consent

0

Number of subjects determined to be ineligible

0

Number of subjects currently active/on study

0

Number of subjects lost to follow-up

0

Number of subjects no longer participating for other reasons

0

Number of subjects who have completed the study

0

Number of subjects who have withdrawn from the study

0

Race:

American Indian or Alaskan Native

0

Asian

0

Black or African American

0

Native Hawaiian or Pacific Islander

0

White

0

Other

0

Unknown or Not Reported

0

Ethnicity:

Hispanic or Latino

0

Not Hispanic or Latino

0

Gender

Male

0

Female

0

Other

0

Unknown / Not Reported

0

Total

0

Vulnerable Populations

Has your study enrolled pregnant woman?*

No

Has your study enrolled prisoners?*

No

Has your study enrolled children?*

No

Subject Withdrawal

How many subject voluntarily withdrew from the study?

0

How many subjects were withdrawn from the study at the request of the PI/Co-PI?

0

Number of subjects withdrawn due to adverse events/unanticipated problems

0

Subject withdraw reason*
If subjects voluntarily withdrew or were withdrawn, please indicate the reasons.

Issues with recruitment/retention, informed consent, or other issues
If applicable, please provide a brief summary of any difficulty you experienced obtaining/retaining subjects or obtaining informed consent during the entire approval period. Additionally, please indicate if there have been any complaints about the research.

Informed Consent Process*
Recognizing that informed consent encompasses much more than a form or document there are a number of methods employed to educate a potential subject as to what is involved in a particular research project. The forms used are one method for documenting the informed consent process.Is written informed consent required for this project?
No

Is written HIPAA authorization required?*

No

New Findings

Significant preliminary observations/interim findings
Have there been any significant preliminary observations/interim findings during the past approval period. If yes, please describe below.

DMC or DSMB exists*
Does a data monitoring committee (DMC) or data and safety monitoring board (DSMB) exist?
No

DMC or DMB Report Status

The following documents are currently attached to this item:

There are no documents attached for this item.

Multi-site trial summary
If this study is a multi-site trial, provide a narrative summary of any relevant reports that have been received in the past year, regardless of whether the report has been previously submitted to the IRB.

Disclosure of Significant Financial Interests*
Investigators (persons responsible for the design, conduct or reporting of this research protocol) must disclose any of the following financial interests / relationships with any entity that sponsors, provides support, or otherwise has a financial interest in the conduct or outcome of this research protocol (Outside Organization): Payments received for the past 12 months from a publicly traded Outside Organization for personal services (e.g., consulting, lecturing / speaking, service on the Scientific Advisory Board) plus the value of any current equity that when aggregated exceeds $5,000Payments received for the past 12 months from a non-publicly traded Outside Organization for personal services that in total exceed $5,000, or having any equity interestMembership on the governing board of any Outside Organization, including service on its board of directors, or having a position of authority or responsibility to act in its best interests, including being an officer, manager, partner, or limited liability company member with management responsibilityInvestigators must also disclose any financial interest in a drug, device or other product or a competing product (IP rights), regardless of whether the IP has been patented, licensed, or assigned to the Penn, if such IP is being tested, evaluated, or developed in, or if its commercial value could be affected by, this protocol.Investigators are not required to disclose equity in mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.Does any Investigator (or his or her spouse or dependent children) have a SIGNIFICANT FINANCIAL INTEREST, as defined above?
Yes

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials and the Financial Disclosure Policy for Research and Sponsored Projects with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Study Completion / Expiration

Study Complete*
Is this study complete?
No

Study Complete - Explanation
If study is completePlease indicate why (eg., research related activities and data analysis are complete, required number of subjects reached, issues with protocol safety,etc.)

The following documents are currently attached to this item:

There are no documents attached for this item.

IRB Approval Expired*
Has IRB approval for this protocol expired or will it expire before the scheduled IRB review?
No

Research During IRB Approval Lapse
If the IRB approval for the protocol has expired or will expire before the scheduled IRB review, confirm that no research related activities occurred/will occur without approval from the IRB unless the PI contacted the Office of Regulatory Affairs and the IRB Executive Chair (or authorized designee) determined that it is in the best interest of subjects to continue during the lapse in IRB approval. For example, in a clinical trial there are (1) subjects who are enrolled but not on intervention, (2) subjects who are on intervention, and (3) subjects who have completed the intervention phase and are in follow up. The IRB Executive Chair must evaluate each of these groups separately regarding continuation of participation in the research after IRB approval has expired.Have any research activities occurred, or will any research activities need to occur, during the lapse in IRB approval?
No

Unanticipated Problems*
Since the last IRB Review, have there been any unanticipated study related events that have not been previously reported to the IRB?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Adverse Events*
Since the last IRB review, has the profile of adverse events (in terms of frequency, severity, or specificity) changed from previous experience or as documented in the research protocol, informed consent document, or investigator's brochure?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Documents attached from the IRB protocol application.

The following documents are currently attached to this item:

Informed consent form (psychosocialandbehavioralaspectsofbariatricsurgery_hipaa_06.13.16.docx)

Informed consent form (psychosocialr01_penn_consent-hippa_01.20.17.clean.doc)

Informed consent form (consenttorecord.doc)

Informed consent form (psychosocialandbehavioralaspectsofbariatricsurgery_consentform_1.31.17clean.docx)

Informed consent form (psychosocialandbehavioralaspectsofbariatricsurgery_consentform_01.31.17clean__spanish.docx)

Informed consent form (templeconsentforaudiorecording.docx)

Informed consent form (consentforaudiorecording_spanish2017.03.23.docx)

Informed consent form (psychosocialandbehavioralaspectsofbariatricsurgery_hipaa_spanish_2017.02.10.docx)

Full sponsor's protocol (impulsvity_r01_tu_irb_2018.08.29clean.docx)

List of Documents Details
Please detail the rationale for why any of the above documents are not attached to the submission (i.e.
No Investigator's Brochure, Protocol, or Consent Forms are utilized for this protocol).

Protocol Details

Resubmission*
Yes

Study Personnel

Principal Investigator

Name:	**ALLISON, KELLY C**
Dept / School / Div:	**4429 - PS-Weight Disorders**
Campus Address Mail Code	**6021**
Address:	**3535 MARKET ST SUITE 3021**
City State Zip:	**PHILADELPHIA PA 19104-3309**
Phone:	**215-898-2823**
Fax:	**215-898-2878**
Pager:	
Email:	**kca@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**03/06/2017**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**MCCUEN-WURST, COURTNEY E**
Dept / School / Div:	**4429 - PS-Weight Disorders**
Campus Address Mail Code	**3309**
Address:	**3535 Market Street, 3rd floor**
City State Zip:	**PHILADELPHIA PA 19104-3309**
Phone:	**-**
Fax:	**-**
Pager:	
Email:	**cmccuen@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**01/13/2019**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Other Investigator

Name:	**WADDEN, THOMAS A**
Dept / School / Div:	**4429 - PS-Weight Disorders**
Campus Address Mail Code	**6021**
Address:	**3535 MARKET ST., 3RD FLOOR**
City State Zip:	**PHILADELPHIA PA 19104-6021**
Phone:	**215-243-7314**
Fax:	**215-898-2878**
Pager:	
Email:	**WADDEN@MAIL.MED.UPENN.EDU**
HS Training Completed:	**Yes**
Training Expiration Date:	**02/13/2017**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Responsible Org (Department/School/Division):

4429 - PS-Weight Disorders

Key Study Personnel

Name:	**ASHARE, REBECCA L**
Department/School/Division:	**PS-Center for Tobacco Research**
HS Training Completed:	**Yes**
Training Expiration Date:	**07/16/2017**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SPITZER, JACQUELINE**
Department/School/Division:	**Health System**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**WILLIAMS, NOEL**
Department/School/Division:	**SU-Surgery Administration**
HS Training Completed:	**Yes**
Training Expiration Date:	**07/14/2018**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Social and Biological Sciences

Study Instruments
Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.
Impulsivity: Impulsivity measures will be administered via study laptops in a quiet laboratory testing room at the following time points: baseline and 6, 12, and 24 months after surgery. All tasks are programmed in E-Prime 2.0 (Psychology Software Tools, Inc.). Total administration time is approximately 25 minutes. The tasks are: Stop Signal Task (SST)117: measure of response inhibition which has been used in previous studies of smoking behavior118-120 and obesity.71,72 In this task, participants respond to left and right-facing arrows (go signal) on the computer screen. On 25% of trials, a stop signal (an 800-Hz, 100-ms, 70-dB tone) is presented indicating that the participant should inhibit a response. The initial stop delay in each block is 250ms and adjusts ±50ms depending on whether the participant successfully inhibits.117 Participants complete three 64-trial task blocks. Trials consist of a 500-ms warning stimulus, a 1,000-ms go signal, and 1,000-ms blank screen inter-trial interval. Task duration is approximately 10 min. The primary outcome is stop signal reaction time (SSRT), calculated as the mean RT on go-trials (MRT) minus mean stop delay (MSD). Stroop Test: measure of interference control, or the ability to suppress habitual responses.121 Higher Stroop interference scores are associated with obesity122,123 and disinhibition as assessed by this subscale of the Eating Inventory.124 Participants view a series of words on a computer monitor and using the keyboard, are asked to press the key associated with the color of the word rather than the word itself. Congruent trials are trials in which the word and color match (e.g., the word green appears in the color green). Incongruent trials are trials in which, the words are printed in colors that do not match the colors of the words (e.g., the word "red" might appear in green). Correct responses and reaction time (RT) for congruent and incongruent trials are recorded. The primary outcome is the interference score, which is also calculated as RT(incongruent) minus RT(congruent) and measures the ability to suppress a habitual response in favor of an unusual one, taking into account overall speed of naming. Delay Discounting Task (DDT): participants choose between a smaller reward available immediately (e.g., $20 today) and a larger reward available after a longer delay (e.g., $40 in a month). People differ in their degree of delay discounting, the extent to which they forgo larger monetary magnitudes in the future in order to obtain immediate rewards. As in previous work, the immediate reward will be fixed and the magnitude and delay of the larger, later reward will vary from trial to trial. Participants will make 51 choices. The primary outcome will be the subjects discount rate, which will be estimated by fitting a logistic regression that assumes a persons decisions are a stochastic function of the difference in subjective value between the two options.127 Keeping with standard behavioral findings128,129 we will assume that subjective value (SV) is a hyperbolic function of the reward amount (A) and delay (D): $SV = A/(1+kD)$, where k is the participants discount rate. Larger values of k indicate a greater degree of discounting future rewards. A composite measure of impulsivity will be calculated by averaging individual z-scores derived from the SST, Stroop interference score, and k-value. We predict that higher levels of impulsivity indicating poor response inhibition and greater discounting of future rewards (i.e., slower SST, higher Stroop interference score, and higher k-values) will be associated with less weight loss 24 months following bariatric surgery. Psychopathology: Psychopathology measures will be

administered via interview or questionnaire at the following time points: baseline and 6, 12, and 24 months after surgery. The tasks are: Structured Clinical Interview for the DSM-5, Research Version (SCID-5-RV)129 is a semistructured interview for making DSM-5 diagnoses for mood, anxiety, eating, substance use, and psychotic disorders. A trained clinician or mental health professional who is familiar with the DSM-5 classification and diagnostic criteria administers the measure, which takes about 2.5 hours. Beck Depression Inventory-II (BDI-II)130: survey used to measure mood. It is the most widely-used measure of depressive symptomatology. Alcohol Use Disorders Identification Test (AUDIT)164: assesses the presence of alcohol use disorders before and after surgery. The Drinker Inventory of Consequences131 is a self-administered 50-item questionnaire designed to measure adverse consequences of alcohol use in five areas: Interpersonal, Physical, Social, Impulsive, and Intrapersonal. Each scale provides a lifetime and past 3-month measure of adverse consequences, and scales can be combined to assess total adverse consequences. The Fagerström Nicotine Tolerance Questionnaire132 is an 8-item, self-report designed to measure physical dependence to nicotine. Urine Drug Screens: collected in temperature sensing cups to ensure valid samples. Urines will be tested for common drugs of abuse (cocaine, opiates, amphetamines, methamphetamine, marijuana). A composite measure of psychopathology will be calculated by averaging individual z-scores derived from the presence/absence of DSM diagnoses, the BDI-II score, and the substance use measures. We predict that higher levels of psychopathology will be associated with less weight loss 24 months following bariatric surgery. Eating Behavior: Eating behavior measures will be administered via interview or questionnaire at the following time points: baseline and 6, 12, and 24 months after surgery. Total administration time is approximately 30 minutes. The tasks are: The Eating Inventory134: 51-item self-report inventory that measures three factors related to eating behavior: 1) cognitive restraint, 2) disinhibition, and 3) hunger. Eating Disorders Examination-Bariatric Surgery Version135: Identical to the widely-used Eating Disorders Examination but also measures eating disturbances specific to bariatric surgery by adding specific questions regarding dumping, plugging, chewing and spitting, and vomiting. (Note. The diagnosis of BED will be established from the SCID interview. The results of the EDE-BSV will be used as a continuous variable in the analyses described below.) Night Eating Questionnaire (NEQ)127: 14-item scale that measures symptoms of night eating and has been used in bariatric populations previously. Yale Food Addictions Scale136: 25-item mixed response scale that is used to identify those who are using high sugar/high fat foods in ways similar to symptoms that are markers of substance use, such as tolerance, withdrawal, and loss of control. A composite measure of disordered eating will be calculated by averaging individual z-scores derived from these measures. We predict that higher levels of disordered eating will be associated with less weight loss 24 months following bariatric surgery. Weight: Weight will be measured with a calibrated digital scale with subjects dressed in light clothing and without shoes. Percent weight loss will be calculated from participants current weight (at each assessment point) as compared to their baseline weight. Participants with higher levels of impulsivity, psychopathology, and disordered eating are predicted to lose less weight at 24 months as compared to those with lower levels. Psychosocial Status: Medical Outcomes Study 36-Item Short Form Survey (SF-36)137: used to measure quality of life Impact of Weight on Quality of Life-Lite (IWQOL-Lite) 138: used to measure quality of life Dietary Intake: ASA-24: public-access, freely available (through the National Cancer Institute), web-based tool to obtain high-quality dietary intake data with minimal bias, making it a preferred tool for studying diet and disease associations.139 These 24-hour food recalls will be conducted at each time point for one weekday and one weekend day. Physical Activity: College Alumnus Survey (commonly known as the Paffenbarger Survey140): calculate self-reported leisure time physical activity kilocaloric expenditure per week. The frame of reference will be the past 6 months. This survey has excellent reliability and validity, including predictive validity for cardiovascular disease outcomes, and compares favorably to 7 day recall. (Note. We acknowledge that objective measures of physical activity have been found to be more reliable in bariatric samples.141 However, as change in physical activity is an outcome of secondary interest, we have elected to use a well-known self-report measure. We hypothesize that changes in quality of life, dietary intake, and physical activity will be associated with changes in weight. Social Support: The Medical Outcomes Study Social Support Survey is a brief, multidimensional, self-administered, social support survey that was developed for patients in the Medical Outcomes Study (MOS), a two-year survey that was developed for patients with chronic conditions. This survey was designed to explore various dimensions of functional social support, including emotional/informational support, tangible support, affectionate support, and positive social interaction. Sherbourne and Stewart (1991) found that the support measures are reliable (all Alphas 0.91), and are fairly stable over time. Selected construct validity hypotheses have been supported. Healthcare Utilization: This information will be extracted from electronic medical records (EMRs) for the following services: primary care, hospitalizations, and emergency room visits. Total number of visits and number of visits to each service will be calculated for all-cause,

mental health, T2D, and hypertension related, separately. Duration of stay will also be assessed.41,42 Based on previous experience of the research team, over 70% of participants will receive their non-bariatric care in the TU or Penn systems during the study. Therefore, we will be able to obtain utilization records through the EMR. However, to ensure complete data capture, we will also use a standardized and validated method employed in the Action for Health in Diabetes (Look AHEAD) study which assesses health services utilization using interviews at study visits. Wood-4 Medication Adherence Scale, a 4-item self-report questionnaire, to assess adherence and provide a way to validate results obtained from the EMR.

Group Modifications

Describe necessary changes that will or have been made to the study instruments for different groups.
We are using the Eating Disorder Examination - Bariatric Surgery Version, which has been used in previous studies of eating behavior in bariatric surgery populations.

Method for Assigning Subjects to Groups

Describe how subjects will be randomized to groups.
****NOTE: THE SURGICAL WEIGHT LOSS INTERVENTION IS NOT A STUDY PROCEDURE. PARTICIPANTS WILL HAVE ALREADY DECIDED TO SEEK SURGERY PRIOR TO THE RESEARCH BEING PRESENTED TO THEM**** We are assessing patients seeking bariatric surgery. There is no division into groups or randomization process.

Administration of Surveys and/or Process

Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.
Individuals interested in bariatric surgery at Penn rst attend an information session at which they are provided an overview of the program. These sessions are led by Dr. Noel Williams, Co-Investigator and Director of the Bariatric Surgery Program, or one of his surgeon colleagues. Those who desire to have surgery schedule an initial consultation with a bariatric surgeon who evaluates their medical appropriateness for surgery. As recommended by the ASMBS and required by third party payers in the region, patients also undergo a psychosocial evaluation which evaluates their psychological appropriateness for surgery and identies behavioral issues that may impact their postoperative outcome. In our program, patients attend 3 to 6 monthly, preoperative weight management (MWM) sessions (the exact number is dictated by each patients insurer). Patients will meet with the research coordinator (RC) approximately 8-10 weeks before surgery at one of their MWM visits, who will introduce the study and describe its goals and requirements. Similarly, at the Temple Health Bariatric Surgery Program, participants will be introduced to the study by the RC at their pre-operative nutrition class or one of their MWM sessions. The population of Spanish-speaking patients at Temple Health is higher than that of Penns program. At Temple Health only, we will provide participants with the option of participation in the study using Spanish language forms. A Spanish consent form will be provided and these will be reviewed by a Spanish speaking Research Coordinator. All other research procedures described below will be the same as those at already approved at Penn and Temple. If patients express interest in participation, the RC will conduct a brief screen to assess eligibility. At this screening visit, candidates will meet individually with the research coordinator, who will explain the study and obtain participants informed consent. Medical history and physical information as well as the Beck Depression Inventory II, The Weight and Lifestyle Inventory, height, weight will be reviewed from the Bariatric Surgery Program. If patients meet the inclusion criteria, they will give their written informed consent to participate and will be scheduled for baseline assessments (described below) which will be coordinated with their next preoperative weight management session, if possible. Prior to this session, the RC will review the patients medical records and meet with the Principal Investigator and research team to

confirm that the participant is eligible and appropriate for the study. After participants complete the screening procedures described above, provide their informed consent to participate, and are enrolled into the study, they will complete four study assessment visits over 24 months. The first visit or baseline visit (Month 0) will occur within approximately 2-8 weeks of bariatric surgery. Subsequent visits will occur at 6, 12, and 24 months follow-up. Follow-up assessments will occur within an approximate 8-week window that includes 4 weeks on either side of the target date. The procedures to be completed in preparation for each of these visits are described below. Throughout participation in the study, participants medical records will be reviewed and data will be collected to obtain psychological diagnoses (including any psychiatric medications the participant is taking), appointment dates for the bariatric surgery program (to track progress through to surgery), and date and type of bariatric surgery. Assessment Visits Participants will complete the following assessments at baseline, and 6, 12, and 24 months after surgery. Participants whose surgery date is scheduled greater than 90 days after their baseline assessment (due to delays in scheduling surgery) may be asked to return to the clinic to complete a portion of the assessment. Participants will be asked to complete the ASA 24 hour dietary food recall and the impulsivity tasks (described above) within approximately 2-8 weeks prior to surgery in order to ensure that these data are within the appropriate time frame prior to surgery. We anticipate that this portion of this assessment will take approximately one hour to complete. If participants are willing to return to the clinic to complete these two portions of the assessment, they will be compensated $25 for their time. Prevalence and Control of Chronic Diseases: 1) T2D will be identified using hemoglobin A1c (HbA1c) and glucose measurements obtained from fasting blood samples, and will be defined as HbA1c 6.5% and glucose 7.0 mmol/L (126 mg/dL), or use of antidiabetes medication.36 Prevalence will be calculated using number of participants with T2D as the numerator and total number of participants as the denominator. Controlled T2D, among individuals diagnosed with T2D, will be defined as HbA1c 7.0%.36 These labs are drawn as part of standard clinical care and the HbA1c and glucose results will be extracted from the EMR of enrolled participants. Participants will not be asked to have additional blood draws as part of the study. 2) Hypertension: systolic blood pressure (SBP) and diastolic blood pressure (DBP) will be measured using a Dinamap 9300XL monitor.. Using recently updated US guidelines, hypertension will be defined as SBP130 mm Hg, or DBP80 mm Hg, or use of antihypertensive medication.39 Prevalence will be calculated using number of participants with hypertension as the numerator and total number of participants as the denominator. Controlled hypertension, among individuals with hypertension, will be defined as SBP130 mm Hg and DBP80 mm Hg.39 Blood pressure is measured as part of standard clinical care. SBP and DBP will also be extracted from the medical record of enrolled participants from their preoperative testing with the bariatric surgery program as well as their postoperative follow up with the surgical team. Healthcare Utilization: This information will be extracted from electronic medical records (EMRs) for the following services: primary care, hospitalizations, and emergency room visits. Total number of visits and number of visits to each service will be calculated for all-cause, mental health, T2D, and hypertension related, separately. Duration of stay will also be assessed.41,42 Based on previous experience of the research team, over 70% of participants will receive their non-bariatric care in the TU or Penn systems during the study. Therefore, we will be able to obtain utilization records through the EMR.

Data Management

Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.

Data confidentiality x Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. x Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Surveys will be collected through REDCap which is password-protected. x Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information. x Wherever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys. Subject Privacy Privacy refers to the persons desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings

in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology). Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following: What protected health information (PHI) will be collected from subjects in this study. Who will have access to that information and why. Who will use or disclose that information. The rights of a research subject to revoke his or her authorization for use of his or her PHI. In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts will be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period. All participants will be assigned a unique identification number. Results from all measures will be entered into a secure password protected database using the individual identification number. A separate secure database houses names and contact information for follow-up. The computing environment is a secure, heterogeneous, networked system of servers, desktops, and printers, all located on the 10th floor of the Gates Pavilion. Survey data will be housed in the Penn Medicine Redcap database. Authorized members of the research team at Temple have access to this database. Paper charts will be housed at Temple University for all participants. The data that will be analyzed for this study do not include any of the 18 identifiers defined by HIPAA. Subject Confidentiality Code numbers will be assigned to each subject to maximize anonymity when entering and analyzing data. All data collected will be kept in a locked office, in locked file cabinets and archived after completion of the study.

Radiation Exposure*
Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
Yes

CACTIS and CT Studies*
Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?
No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
Yes

CTRC Resources*
Does the research involve CTRC resources?
No

If the answer is YES, indicate which items is is provided with this submission:

Modified research informed consent document that incorporates HIPAA requirements

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
Yes

Primary Focus*
Survey research (the main focus of the research is administration of a survey to research subjects)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
x	**Diagnostic test/procedure (research-related diagnostic test or procedure)**
	Obtaining human tissue for basic research or biospecimen bank
x	**Survey instrument**
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**STEVENS, KEVIN D**
Dept / School / Div:	**4257 - DM-Pulmonary, Allergy and Critical Care**
Phone:	**215-573-3472**
Fax:	**215-349-8715**
Pager:	
Email:	**sdkevin@upenn.edu**

Department budget code

400 - 400 - 4 - 568335 - 3000 - 2810 - 2947

Funding Sponsors

Name:	**NATIONAL INSTITUTES OF HEALTH**
Type:	**UPENN Federal**

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

Funding sponsors gift
Is this research being funded by a philanthropic gift?
No

Regulatory Sponsor

IND Sponsor

none

400 - 400 - 4 - 568335 - 3000 - 2810 - 2947

Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
Pending

Sponsor Funding
Is this study funded by an industry sponsor?
No

Status of contract

The following documents are currently attached to this item:

There are no documents attached for this item.

Multi-Site Research

Other Sites

Site:	**Temple University**
Contact:	**Jacque Spitzer**
Pi:	**David B. Sarwer, Ph.D.**
Mail:	**Center for Obesity Research and Education** **3223 N. Broad Street, Suite 175** **Philadelphia, PA 19140**
Phone:	**215-707-8633**
Email:	**jacque.spitzer@temple.edu**

Management of Information for Multi-Center Research
All participants will be recruited from Penn Medicine and Temple University's bariatric surgery programs. Temple University will become the data coordinating center and participant charts will be stored at Temple University. The PI, Dr. Sarwer, is now on faculty at Temple University. Dr. Sarwer and his research coordinator, Jacque Spitzer, will be involved in research study meetings, data management, data analysis, and preparation and presentation of study outcomes.

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Abstract
This study will evaluate the relationship between psychopathology, disordered eating, and impulsivity (measured by clinical interview, self-report measures, and objective testing) on changes in weight and

psychosocial status in the first two years after bariatric surgery. Secondary outcomes will include prevalence and control of Type 2 diabetes (T2D) and hypertension, health services utilization, and adherence to antidiabetes and antihypertensive medication. Participants will be 300 adults who plan to undergo bariatric surgery. Participants will complete four assessments over a two-year period, one at baseline (before surgery) and 6, 12, and 24 months after surgery. Each assessment will include computer tasks, surveys, clinical interview, urine test, waist circumference and height/weight measurement. We will track how psychopathology, disordered eating, and impulsivity are related to changes in weight, psychosocial status, and secondary outcomes listed above, following bariatric surgery.

Objectives

Overall objectives
The proposed observational study will evaluate the relationship between measures of psychopathology, disordered eating, and impulsivity, (each assessed preoperatively and in the early postoperative period) and changes in weight and psychosocial status in the first two years after bariatric surgery. Secondary outcomes of prevalence and control of T2D and hypertension, health services utilization, and adherence to antidiabetes and antihypertensive medication will also be assessed. All participants will complete assessments at baseline (before surgery) and at 6, 12, and 24 months follow-up. Secondary aims will examine psychopathology, disordered eating, impulsivity, as well as weight loss, in relation to changes in eating behavior, physical activity, psychosocial status, and substance use in the first two years after bariatric surgery. The study has one specific aim and two secondary aims. Specific Aim 1: To determine the relationship between psychopathology, disordered eating, and impulsivity assessed preoperatively and changes in body weight over the first two years following bariatric surgery. We will determine which individual measures falling under these constructs are important in predicting the relative success of bariatric surgery. We will also examine the relationship of changes in the individual measures (from baseline to 6-months after surgery) on subsequent weight loss. (The study is powered on this aim.) We predict that individual measures of psychopathology, disordered eating, and impulsivity will predict smaller weight losses two years postoperatively. We also predict that smaller changes in measures of impulsivity, psychopathology, and disordered eating within the first 6 postoperative months will be associated with smaller weight losses at postoperative month 24. Secondary Aim 1: To examine the correlation structure among our individual measures, and subsequently will generate and confirm composite measures for the three constructs. Composite measures of psychopathology, disordered eating, and impulsivity will predict smaller weight losses two years postoperatively. We also will estimate the proportion of variance in weight loss accounted for by each composite measure. We predict that confirmatory factor analysis will confirm that our individual measures represent three constructs of psychopathology, disordered eating, and impulsivity. Higher values of these composite measures will in turn predict smaller weight losses at postoperative month 24. Secondary Aim 2: To assess the relationship between baseline measures of interest and postoperative changes in caloric and macronutrient intake, eating behavior, physical activity, and psychosocial status. We predict that participants with greater psychopathology, disordered eating, and impulsivity will report greater caloric intake, less favorable changes in macronutrient intake and eating behavior, participate in less physical activity and report more symptoms of psychosocial distress.

Primary outcome variable(s)
All primary outcomes will be measured at 0, 6, 12, and 24 months postoperatively. Specific Aim 1: weight change

Secondary outcome variable(s)
All secondary outcomes will be measured at 0, 6, 12, and 24 months postoperatively. Secondary aims call for examining relationships between primary outcomes and some additional variables. These additional variables include psychosocial status, dietary intake, physical activity, prevalence and control of T2D and hypertension, health services utilization, and adherence to antidiabetes and antihypertensive medication.

Background
Bariatric surgery is an increasingly utilized treatment for the growing number of individuals with a body mass index (BMI) of 40 kg/m2 or 35 kg/m2 in the presence of obesity-related comorbidities. Early results are promising, with patients losing 20-35% of their initial body weight in the first 6-18 months after surgery and experiencing improvements in obesity-related comorbidities. These outcomes,

however, are not universal and vary between patients and across surgical procedures. It is estimated that 20-30% of patients experience suboptimal weight loss or significant weight regain within the first few postoperative years. Reasons for this are not fully understood, but likely involve both physiological processes and behavioral factors (e.g., difficulty adhering to the dietary and physical activity recommendations made prior to surgery). Extreme Obesity More than one-third of American adults are obese, defined by a body mass index (BMI) of 30 kg/m2.1 Furthermore, 8.3% of women and 4.4% of men are extremely obese, defined by a BMI 40 kg/m2.1 Obesity, and extreme obesity in particular, is associated with major health complications including coronary heart disease, hypertension, type 2 diabetes mellitus, sleep apnea, and osteoarthritis.2-4 Surgical Treatment of Extreme Obesity Bariatric surgery is currently recommended for individuals 18 years and older with a BMI of 40 kg/m2 or those with a BMI of 35 kg/m2 in the presence of significant co-morbidities.5,6 Approximately 200,000 individuals are estimated to undergo bariatric surgery in the United States each year. The most common surgical procedures include the gastric bypass (GB), sleeve gastrectomy (SG), and adjustable gastric banding (AGB).7,8 As of 2013, the GB was the most common procedure in the United States, comprising 56% of all procedures; the SG comprised 36.3%.8 Anecdotal reports suggest that the SG is increasing in popularity while the AGB is now performed infrequently. With all three procedures, patients typically reach their maximum weight loss of 20-35% of body weight 12 months after surgery.3,4,9-16 These weight losses are associated with significant improvements in obesity-related co-morbidities and decreased risk of mortality.3,4,11,17-24 Despite these impressive results, studies have found that approximately 25% of patients who undergo bariatric surgery fail to reach or maintain the expected postoperative weight loss.25-27 Courcolous and colleagues, for example, observed that 23.6% of GB patients regained weight between postoperative year 1 and year 2. Less is known about the typical postoperative weight trajectory of patient who have undergone SG. Recent studies have suggested that weight regain is associated with deterioration of many of the health benefits seen with bariatric surgery.12,28-31 Psychosocial Status and Psychopathology in Candidates for Bariatric Surgery Extreme obesity is associated with a significant psychosocial burden, including impairments in quality of life, body image, sexual behavior and other areas of psychosocial functioning.32 While this distress is believed to contribute to the decision to have bariatric surgery, its impact on postoperative outcomes is less clear. At present, little is known about the physiological and behavioral contributions to success or failure of bariatric surgery.33 Regardless, weight regain after bariatric surgery is frequently attributed to preoperative psychosocial and behavioral factors.27,34-41 More specifically, there has been a great deal of interest in the presence of formal psychopathology in bariatric surgery patients and its potential contribution to postoperative outcomes.42-45 At least six studies have described rates of psychopathology in candidates for bariatric surgery using structured diagnostic instruments.46-51 Lifetime rates of any psychiatric diagnoses ranged from 36.8%-72.6%, higher than those reported in most studies of the general population. Mood disorders were the most frequent diagnoses, seen in 22.0%-54.8% of patients. Substance use disorders (SUDs) were found in up to 35.7% of patients and alcohol abuse or dependence in up to 33.2%. Binge eating disorder (BED), defined as eating an unusually large amount of food within a short period of time coupled with a loss of control over eating, has been diagnosed in 4.6% to 27.1% of patients. Current diagnoses (as compared with lifetime) were less common, reported in 20.9%-55.5% of candidates for surgery. Mood disorders were diagnosed in up to 31.5%. BED ranged from 3.4%-41.9%. Current substance use was seen in less than 2% of patients. (Note. The lower percentages of those with current psychopathology, as opposed to lifetime psychopathology, are expected.) While studies of the psychosocial characteristics of bariatric surgery candidates have been informative, they are not without limitations. Many studies have suffered from methodological concerns, including small sample sizes or lack of an appropriate comparison group. Further, establishing psychiatric diagnoses prior to bariatric surgery is challenging. Perioperative guidelines suggest that patients undergo an evaluation with a mental health professional prior to surgery3 and most third party payers require these evaluations. However, most programs do not use structured clinical interviews to establish diagnoses for clinical purposes.52,53 Several studies have suggested that candidates for bariatric surgery engage in impression management prior to surgery, in which they minimize reports of psychopathology to present themselves to the bariatric team in the most favorable light.54-56 To address this issue, assessment of psychiatric symptoms for research purposes is recommended to occur independently from the required clinical evaluation, as we will do in the proposed study. Nevertheless, studies focusing on the relationship between specific diagnoses and postoperative outcomes may fail to account for other psychological constructs that may be shared across diagnoses. Mood disorders, BED, and SUDs all share the common psychological construct of impulsivity, considered an important aspect of executive functioning. A lack of impulse control may contribute to the excessive weight gain seen in extreme obesity and may impact the results of bariatric surgery. Disinhibition and Impulsivity among Persons with Extreme Obesity Studies have suggested

that individuals with obesity, and in particular those with extreme obesity presenting for bariatric surgery, show some deficits in executive functioning. For example, candidates for bariatric surgery have shown deficits in working memory, mental flexibility, motor speed and complex attention.57,58 These deficits could impact comprehension and retention of information presented to patients during the preoperative consultation process and, thus, negatively impact the ability to adhere to the dietary and behavioral changes required for an optimal postoperative outcome.45 At the same time, metabolic dysregulation, such as insulin resistance or hyperglycemeia seen in type 2 diabetes, also is associated with cognitive deficits, suggesting a potential physiological mechanism for the relationship.59-61 Dietary disinhibition, defined as a loss of control over eating, plays a central role in the overconsumption of food and, subsequently, the development of obesity.62,63 Disinhibition is similar to impulsivity, the term more commonly used in the substance use and smoking cessation literatures. Impulsivity is a multi-faceted construct and refers to the absence of the ability to inhibit an automatic behavior (otherwise known as response inhibition)64,65 and the tendency to discount future consequences in favor of more immediate outcomes (known as delay discounting).66,67 Similar to the role of disinhibition in obesity, impulsivity contributes to the development of and relapse with SUDs. Indeed, response inhibition and delay discounting are associated with both SUDs68-70 and obesity.71,72 Both also predict response to treatment for both SUDs73-75 and obesity.76 Chronic overeating and binge eating share several neurobiological and behavioral similarities with SUDs.77,78 In this regard, both may be viewed as behavioral disorders, in which intake (of food, alcohol, and/or drugs) escalates to a rate that is unhealthy and maladaptive. Nevertheless, the specific nature of the relationship between binge eating and substance use remains to be fully elucidated.79 There are similarities between binge eating and addictive disorders, including craving for the desired substance (drug or highly palatable food), a sense of loss of control when using, repeated attempts to control use despite clear adverse consequences, and the dedication of much time in obtaining and using the substance.80-82 Thus, the disinhibition observed with obesity and binge eating, the impulsivity seen with substance use disorders, and the emotional dysregulation associated with mood disorders all likely share commonalities (dashed lines in Figure 1) that may both contribute to the development of extreme obesity and also may be associated with weight loss (solid lines in Figure 1) and changes in psychosocial status after bariatric surgery. Psychosocial Status and Psychopathology after Bariatric Surgery In general, individuals who undergo bariatric surgery report dramatic improvements in psychosocial status and functioning postoperatively.83,84 The vast majority of patients report significant reductions in symptoms of depression and anxiety in the first postoperative year. They also report significant improvements in health and weight-related quality of life. Patients also report improvements in body image, sexual functioning, and relationship satisfaction.85-87 The relationship between preoperative psychopathology and postoperative outcomes is less robust.34,84 Livhits and colleagues reviewed this literature and concluded that the preoperative factors of BMI, BED, and the presence of personality disorders provided the strongest negative associations with postoperative weight loss.42 At least two studies have suggested that preoperative psychopathology, particularly mood and anxiety disorders, is associated with smaller weight postoperative weight losses.88,89 The relationship between BED and postoperative weight loss is unclear; some studies have found a relationship between preoperative BED and postoperative weight loss90,91 while others have not.92-94 Additionally, two studies have suggested that a history of substance abuse is associated with larger weight losses following bariatric surgery.95,96 The interpretation of this counterintuitive finding is that the self-regulation skills that help patients maintain their sobriety also help patients adhere to the demands of the recommended postoperative diet. Disinhibition and Impulsivity following Bariatric Surgery Encouragingly, studies have shown that there are improvements in executive functioning in persons with extreme obesity in the first two years after bariatric surgery.97,98 Postoperatively, patients typically report decreases in disinhibition and hunger, as well as increases in cognitive restraint.99,100 The physical aspects of bariatric surgery typically prevent individuals from eating the objectively large amount of food necessary to meet the diagnostic criteria of BED. However, many individuals continue to report the feeling of loss of control over their eating.44 The self-reported inability to control these impulses postoperatively is associated with smaller weight losses and greater emotional distress in the first few postoperative years.91,99,101,102 There is additional evidence that patients have difficulty with impulse control after surgery. A number of studies have suggested that there is an increased risk of substance abuse following bariatric surgery.101,103,104 King and colleagues,105 in their seminal investigation, found an increased rate of alcohol use disorder in the second postoperative year as compared to the year prior to surgery or in the first postoperative year. Other recent studies also have found increases in alcohol or composite substance abuse (drug, alcohol, or cigarettes) in the first two years after bariatric surgery.106-108 Postoperative substance use has been associated with smaller postoperative weight losses, postoperative nocturnal eating, and subjective hunger.109 Patients at

greatest risk for new onset SUDs were more likely to report problems with high sugar/low fat food before surgery, further suggesting the role of impulsivity in eating behavior and substance use before and after surgery.110 This increase in substance abuse after surgery has been described as addiction transfer111 and characterized as a modern example of symptom substitution in which abuse of one substance (food) is replaced by another (alcohol or drugs) when patients are unable to consume large amounts of food after surgery.109 A potential contributor to addiction transfer may be emotional dysregulation. In general, symptoms of depression typically improve within the first six months of bariatric surgery as patients are in the period of most rapid weight loss.35 Within the first two postoperative years, the use of anti-depressant medications also decreases; however, a substantial minority of patients report using these medications two years after surgery. As most patients begin to regain weight postoperatively, they also experience an erosion of the improvements in depressive symptoms and quality of life.112 In addition, a higher-than-expected number of postoperative suicides have been documented.17,44 A secondary aim of the proposed study will investigate the relationship between changes in weight during the first two postoperative years and changes in psychosocial status. Summary The relationship between preoperative psychosocial status and postoperative outcomes is one of the holy grail issues in the area of bariatric surgery. Concern about preoperative psychosocial status is one reason that standard clinical practice in the United States requires that individuals who seek bariatric surgery undergo a preoperative psychosocial evaluation (typically a clinical interview that does not include a structured diagnostic assessment) prior to surgery. This evaluation is designed to identify potential psychiatric and behavioral contraindications to surgery (psychosis; severe, untreated depression; active substance abuse; or significant behavioral non-compliance) and also provide patients with psychoeducation on the dietary and behavioral challenges after surgery.113 Prior to surgery, patients also meet with registered dietitians who teach them the basic elements of the postoperative diet and behaviors required for optimal postoperative outcomes. These evaluations exclude relatively few patients for surgery.55,84,114-116 Patients with psychosocial and behavioral issues, such as mood disorders and disordered eating, often are recommended for surgery even in the presence of these concerns. There is some evidence to suggest that a substantial percentage of these individuals subsequently experience smaller than expected weight losses, weight regain, or psychosocial distress after surgery. Patients with a history of psychopathology, specifically those with mood disorders or disordered eating, are vulnerable to returning to maladaptive eating and activity behaviors which likely promoted the development of extreme obesity and may compromise long-term weight control. While investigations of the relationship between specific diagnoses and postoperative outcomes have shed some light on these relationships, we believe that a common psychological construct, impulsivity--an important element of overeating, substance use, and mood disorders--may be a robust predictor of postoperative outcomes along with psychopathology or disordered eating. Few studies have used objective tests of impulse control in individuals undergoing bariatric surgery. To fill this gap, the proposed observational study will evaluate the relationship between measures of psychopathology, disordered eating, and impulsivity, (each assessed preoperatively and in the early postoperative period) and changes in weight and psychosocial status in the first two years after bariatric surgery. Results of this study would provide important information on the role of psychopathology, disordered eating, and impulsivity on outcomes of bariatric surgery and underscore the need for more comprehensive assessment and management of these behaviors before and after surgery.

Study Design

Phase*
Not applicable

Design
Observational assessment study

Study duration
The study period begins December 1, 2015 and ends November 30, 2020. Each participant will be enrolled for approximately 24-30 months. Although each participant will complete his/her study assessments within 24 months, participants may be enrolled for additional months. This extra time will become necessary if a participant is enrolled well before her scheduled surgery date (in many cases, patients receive all preoperative clearances months before their surgery date).

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct

the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.

A list of all study personnel is provided below, along with their qualifications and roles in the research, and the amount of effort that they will devote to this project. We attest that there is sufficient time to conduct and complete the research. Kelly C. Allison, PhD, Site-Principal Investigator, Dr. Allison is Associate Professor of Psychology in Psychiatry at the Perelman School of Medicine at the University of Pennsylvania. She has actively collaborated with Sarwer and Wadden on a number of research projects over the past decade. Dr. Allison been a co-investigator for related studies that: examine changes in neural response to food stimuli among bariatric surgery patients as compared to controls (R01-DK085615, Wadden, Gur); compare the effect of weight loss through behavioral counseling vs. bariatric surgery on reproductive functioning among women (ASMBS grant, PI: Sarwer) and examine eating and dietary behavior in the Teen LABS study (R01-DK080738 (PI: Sarwer). She also has a wealth of clinical experience with the psychosocial and behavioral aspects of bariatric surgery. Clinically, she provides pre-surgical psychological evaluations for bariatric patients and individual psychotherapy to patients who struggle with weight regain after surgery. Her experience with the assessment of disordered eating behavior played an important role in the development of this application. She will actively participate in recruiting participants, training and supervising the assessors, reviewing and interpreting assessment results, and preparing the main manuscripts. Rebecca Ashare, PhD, Co-Investigator. Dr. Ashare is Assistant Professor of Psychology in Psychiatry at the Perelman School of Medicine at the University of Pennsylvania. She is a faculty member of the Center for Interdisciplinary Research on Nicotine Addiction (CIRNA). Her research focuses on identifying novel therapeutic targets that may represent risk factors for smoking relapse and evaluating novel treatments to improve abstinence rates. She conducts human behavioral pharmacology studies in nicotine dependence and utilizes tools from the fields of neuropharmacology and cognitive neuroscience to understand the mechanisms of efficacy of nicotine dependence treatments. Much of this work focuses on cognition and impulsive decision-making, which is hypothesized to play a central role in weight regain after bariatric surgery. She also has a wealth of experience with the psychometric assessment battery in the proposed study. She will participate in weekly meetings of the research team and have responsibility for the administration and interpretation of the neurocognitive assessments. She also will actively participate in the preparation of the manuscripts that result from the proposed study. Thomas A. Wadden, PhD, Co-Investigator. Dr. Wadden is Professor of Psychology and Director of the Center for Weight and Eating Disorders at the University of Pennsylvania School of Medicine. He is internationally known for his work on the etiology and treatment of obesity, including projects investigating the psychosocial and behavioral aspects of bariatric surgery. As detailed in his biographical sketch, he has extensive history of NIH funding for his research and has collaborated with Dr. Sarwer for the past 19 years. He has made significant intellectual contributions to this program of research the design of the present study. He will attend weekly meetings of the research team to review and interpret the results from the study assessments and to plan strategies for participant recruitment. He also will collaborate on the preparation of publications at the end of the study. Noel Williams, PhD, Co-Investigator. Dr. Williams is Clinical Professor of Surgery at the University of Pennsylvania and Director of the Bariatric Surgery Program at the Hospital of the University of Pennsylvania. He has collaborated with Drs. Sarwer and Wadden on their research in the area of bariatric surgery for the past 13 years. Dr. Williams will be responsible for reviewing the surgical and medical records of all potential participants to confirm that they are medically appropriate for participation. He also will be responsible for the extraction of surgical data from patients medical records which will be investigated in exploratory analyses. He will participate in regularly scheduled meetings of the research team. Courtney McCuen-Wurst, PsyD, Postdoctoral Researcher, Study Assessor. Dr.. McCuen-Wurst will serve as the study assessor for this study. She has extensive experience with the dietary and behavioral issues of overweight and obese patients. She also completed a previous practicum at the Center for Weight and Eating Disorders. She will primarily be responsible for recruiting patients and conducting the clinical assessments of patients scheduled for their study assessments for this study. David B. Sarwer, PhD, Principal Investigator (contact PI), Dr. Sarwer is the Associate Dean for Research and Director of the Center for Obesity Research and Education at Temple Universitys College of Public Health. He completed a Patient-Oriented Mentored Research Scientist Award funded by NIDDK (K23-DK60023). One of the studies supported by that award investigated changes in psychosocial status, dietary intake, and eating behavior in adults who underwent bariatric surgery. He also completed a pilot study (R03-DK067885) investigating the efficacy of dietary counseling in improving outcomes of bariatric surgery. Dr. Sarwer has served or currently serves as the Principal Investigator on three other

NIH funded studies in the area of bariatric surgery. One ongoing investigation is an ancillary study to the Teen-LABS bariatric surgery consortium and is investigating changes in dietary intake and eating behavior in adolescents who undergo bariatric surgery (R01-DK080783). A recently completed project was an ancillary study to the adult LABS consortium which investigated changes in sexual and marital function following bariatric surgery (R01-DK072452). The third study (RC1-DK086132) was designed to compare improvements in diabetes control in obese diabetic individuals who are assigned by chance to one of three groups: 1) Roux-en-Y gastric bypass; 2) laparoscopic adjustable gastric banding; or 3) intensive non-surgical weight management. Dr. Sarwer will be responsible for overseeing all aspects of the proposed study. He will lead weekly meetings of the Penn and Temple research team (including other Key Personnel and the Research Coordinator) to review weekly progress of the study. He will meet weekly with the Research Coordinator (Ms. Hopkins) to review participant recruitment, retention, and successful completion of scheduled study assessments. In the final year he will be responsible for interpretation of the results of the study as well as the preparation of manuscripts and competitive renewal grant applications. Michael Edwards, MD, Dr. Edwards is the Chief of the General and Minimally Invasive Surgery Division as well as the Director of the Temple University Hospital Bariatric Surgery Program. Dr. Edwards will be responsible for reviewing the surgical and medical records of all potential Temple University participants to confirm that they are medically appropriate for participation. He also will be responsible for the extraction of surgical data from patients medical records which will be investigated in exploratory analyses. Jacque Spitzer, MSEd, Project Director. Ms. Spitzer will serve as the Temple University Project Director for this study. She has extensive experience coordinating the activities of research projects related to surgical and behavioral weight loss. She worked at the Center for Weight and Eating Disorders at the University of Pennsylvania with Drs. Sarwer, Wadden and Allison for several years and recently joined the Center for Obesity Research and Education. She will primarily be responsible (along with Dr. Sarwer) for the oversight and implementation of the study. This will include managing IRB submissions and communications, oversight of participant recruitment and retention and management of the study team at University of Pennsylvania and Temple University. She will also serve as an assessor for the clinical interviews to be conducted at the assessment visits. Jingwei Wu, PhD, Co-Investigator. Jingwei Wu is an assistant professor in the Department of Epidemiology and Biostatistics at Temple University. Before joining Temple, he served as primary biostatistician and statistical consultant at Indiana University School of Medicine since 2001, worked on investigations in multiple biomedical areas, including hypertension, pain/depression/anxiety, sexually transmitted infections, medication compliance, health-related quality of life outcomes, cancer surveillance, and clinical trials. He also served as senior biostatistician in Hoosiers Oncology Group, to evaluate innovative and promising drugs, methods and approaches to cancer treatment through, among other things, clinical research. Besides that, he provided statistical support for faculties in the development and conduct of research and scholarly activities that advance medical science through expansion of internal/external funding. During the course of this study, Dr. Wu will take part in team meetings, advise on study design, establish the randomization stream for the study, generate interim data reports for safety monitoring, write the analysis plan, and carry out the analysis at the appointed times. He will also take part in the writing of annual reports, and in the writing of manuscripts for publication. Caitlin LaGrotte, PsyD, Postdoctoral Researcher, Study Assessor. Dr. Caitlin LaGrotte will serve as the study assessor for this study at Temple University. She has extensive experience with the dietary and behavioral issues of overweight and obese patients. She previously worked at the Center for Obesity Research and Education. She will primarily be responsible for conducting the clinical assessments of patients scheduled for their study assessments for this study. Gabriel S. Tajeu, DrPH, Administrative Supplement Investigator. Dr. Tajeu is an Assistant Professor in the Department of Health Services Administration and Policy at Temple University. During his doctoral training, he conducted research on data fidelity in the obesity literature, the association of sleep with distracted eating and drinking, and also examined the cost-effectiveness of antihypertensive medications. As a postdoctoral fellow, he conducted epidemiologic and outcomes research on hypertension and cardiovascular disease. Dr. Tajeus work is currently focused on cardiovascular disease risk reduction. He will be responsible for assessing secondary study outcomes of T2D and hypertension prevalence and control, health services utilization, and adherence to antidiabetes and antihypertensive medication following bariatric surgery. Dr. Tajeu will participate in team meetings and be directly mentored by Dr. Sarwer. Megan Bookhout, PhD, Postdoctoral Researcher, Study Assessor. Dr. Megan Bookhout will serve as a study assessor for this study. She has extensive experience with clinical assessment and diagnostic interviewing, and has worked with many overweight and obese patients in both clinical and research contexts. She will primarily be responsible for conducting the clinical assessments of patients scheduled for their study assessments for this study.

Characteristics of the Study Population

Target population
Adults aged 18-65 years old who plan to undergo one of two bariatric surgeries, either Rous-en-Y Gastric Bypass (RYGB) or Laparoscopic Sleeve Gastrectomy (LSG) at the University of Pennsylvania Health System. Based on our previous studies of bariatric surgery patients, we expect that approximately 80% of participants will be women and 20% of participants will be ethnic minorities.

Subjects enrolled by Penn Researchers
300

Subjects enrolled by Collaborating Researchers
0

Accrual
Participants will be recruited from the Bariatric Surgery Programs at the Hospital of the University of Pennsylvania and Presbyterian Medical Center, all part of Penn Medicine. We will enroll participants until a total of 300 adults have completed baseline visits. We anticipate that we will need to consent a larger number of participants in order to meet this enrollment goal. Based on our previous studies of bariatric surgery patients, we expect that approximately 80% of participants will be women and 20% of participants will be ethnic minorities. Dr. Noel Williams, Director of the Bariatric Surgery Program, conducts approximately 300 bariatric surgery operations per year. Additional surgeons in the Bariatric Surgery Program (at the Hospital of the University of Pennsylvania, Presbyterian Medical Center, and Pennsylvania Hospital) operate on approximately 200 patients per year. In order to increase the diversity and size of our sample, participants will also be recruited from the Temple Health Bariatric Surgery Program. The patient flow at Temple Health is similar to that of the Penn Health System (described below). Participants will be approached by the Research team during their pre-operative testing and education process.

Key inclusion criteria
We seek to enroll a sample of patients that is representative of those who present for bariatric surgery. We have based our exclusion criteria for the study largely on the clinical criteria used for bariatric surgery as well as our previous studies with bariatric patients. Inclusion Criteria: Adults aged 18-65 years old 18 years of age or above BMI of 35-60 kg/m2 (or 35 kg/m2 in the presence of significant weight-related comorbidities, including established coronary artery disease, established peripheral arterial disease, symptomatic carotid artery disease, sleep apnea, metabolic syndrome, cardiomyopathy, hypertension, and debilitating joint pain).

Key exclusion criteria
Uncontrolled hypertension (systolic blood pressure 160 or diastolic blood pressure 100mmHg) HbA1c 11% Recent history of cardiovascular disease (myocardial infarction or stroke within the past 6 months) Clinically significant hepatic or renal disease Long-term treatment with oral steroids Current use of weight loss medication (OTC or prescription) Psychiatric hospitalization in the past 6 months Psychiatric diagnosis that would contraindicate surgery (e.g., schizophrenia) History of bariatric surgery Non-ambulatory individuals, defined as those who are unable to walk without a cane or walker. Lack of capacity to provide informed consent Plans to relocate from the area within 2 years Principal Investigator discretion For the cognitive, computer based testing: Any impairment (physical and/or neurological) including visual or other impairment preventing cognitive task performance Hearing impairment, significant hearing loss (more than 20% in either ear), cochlear implants, or bi-lateral hearing aids (will be assessed on a case-by-case basis to determine whether participants are eligible to complete the Stop Signal Task Color Blindness (will be assessed on a case-by-case basis to determine whether participants are eligible to complete the Stroop Task)

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
n/a

Subject recruitment
Individuals interested in bariatric surgery at Penn rst attend an information session at which they are provided an overview of the program. These sessions are led by Dr. Noel Williams, Co-Investigator and Director of the Bariatric Surgery Program, or one of his surgeon colleagues. Those who desire to have surgery schedule an initial consultation with a bariatric surgeon who evaluates their medical appropriateness for surgery. As recommended by the ASMBS and required by third party payers in the region, patients also undergo a psychosocial evaluation which evaluates their psychological appropriateness for surgery and identies behavioral issues that may impact their postoperative outcome. In our program, patients attend 3 to 6 monthly, preoperative weight management (MWM) sessions (the exact number is dictated by each patients insurer). Patients will meet with the research coordinator (RC) approximately 8-10 weeks before surgery at one of their MWM visits, who will introduce the study and describe its goals and requirements. Similarly, at the Temple Health Bariatric Surgery Program, participants will be introduced to the study by the RC at their pre-operative nutrition class or one of their MWM sessions. The population of Spanish-speaking patients at Temple Health is higher than that of Penns program. At Temple Health only, we will provide participants with the option of participation in the study using Spanish language forms. A Spanish consent form will be provided and these will be reviewed by a Spanish speaking Research Coordinator. All other research procedures described below will be the same as those at already approved at Penn and Temple. If patients express interest in participation, the RC will conduct a brief screen to assess eligibility. At this screening visit, candidates will meet individually with the research coordinator, who will explain the study and obtain participants informed consent. Medical history and physical information as well as the Beck Depression Inventory II, The Weight and Lifestyle Inventory, height, weight will be reviewed from the Bariatric Surgery Program. If patients meet the inclusion criteria, they will give their written informed consent to participate and will be scheduled for baseline assessments (described below) which will be coordinated with their next preoperative weight management session, if possible. Prior to this session, the RC will review the patients medical records and meet with the Principal Investigator and research team to conrm that the participant is eligible and appropriate for the study. After participants complete the screening procedures described above, provide their informed consent to participate, and are enrolled into the study, they will complete four study assessment visits over 24 months. The first visit or baseline visit (Month 0) will occur within approximately 2-8 weeks of bariatric surgery. Subsequent visits will occur at 6, 12, and 24 months follow-up. Follow-up assessments will occur within an approximate 8-week window that includes 4 weeks on either side of the target date. The procedures to be completed in preparation for each of these visits are described below. Throughout participation in the study, participants medical records will be reviewed and data will be collected to obtain psychological diagnoses (including any psychiatric medications the participant is taking), appointment dates for the bariatric surgery program (to track progress through to surgery), and date and type of bariatric surgery.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?

No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

Participants will receive $100 for the baseline assessment and $50 of participant payments for the 6- and 12- month visits, and $100 for the 24-month visit, for a total of $300 over the course of the study. Participants will also receive compensation for parking/travel. Each visit lasts approximately 4 hours. If participants do not complete all study visits, they will receive compensation based on the number of visits completed. Participants will receive an additional $25.00 gift card if they are requested to return for repeat measures.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
****NOTE: THE SURGICAL WEIGHT LOSS INTERVENTION IS NOT A STUDY PROCEDURE. PARTICIPANTS WILL HAVE ALREADY DECIDED TO SEEK SURGERY PRIOR TO THE RESEARCH BEING PRESENTED TO THEM**** Participants will complete the following assessments at baseline, and 6, 12, and 24 months after surgery. The measures that will be used at each assessment are described below: Impulsivity: Impulsivity measures will be administered via study laptops in a quiet laboratory testing room at the following time points: baseline and 6, 12, and 24 months after surgery. All tasks are programmed in E-Prime 2.0 (Psychology Software Tools, Inc.). Total administration time is approximately 25 minutes. The tasks are: Stop Signal Task (SST)117: measure of response inhibition which has been used in previous studies of smoking behavior118-120 and obesity.71,72 In this task, participants respond to left and right-facing arrows (go signal) on the computer screen. On 25% of trials, a stop signal (an 800-Hz, 100-ms, 70-dB tone) is presented indicating that the participant should inhibit a response. The initial stop delay in each block is 250ms and adjusts ±50ms depending on whether the participant successfully inhibits.117 Participants complete three 64-trial task blocks. Trials consist of a 500-ms warning stimulus, a 1,000-ms go signal, and 1,000-ms blank screen inter-trial interval. Task duration is approximately 10 min. The primary outcome is stop signal reaction time (SSRT), calculated as the mean RT on go-trials (MRT) minus mean stop delay (MSD). Stroop Test: measure of interference control, or the ability to suppress habitual responses.121 Higher Stroop interference scores are associated with obesity122,123 and disinhibition as assessed by this subscale of the Eating Inventory.124 Participants view a series of words on a computer monitor and using the keyboard, are asked to press the key associated with the color of the word rather than the word itself. Congruent trials are trials in which the word and color match (e.g., the word green appears in the color green). Incongruent trials are trials in which, the words are printed in colors that do not match the colors of the words (e.g., the word "red" might appear in green). Correct responses and reaction time (RT) for congruent and incongruent trials are recorded. The primary outcome is the interference score, which is also calculated as RT(incongruent) minus RT(congruent) and measures the ability to suppress a habitual response in favor of an unusual one, taking into account overall speed of naming. Delay

Discounting Task (DDT): participants choose between a smaller reward available immediately (e.g., $20 today) and a larger reward available after a longer delay (e.g., $40 in a month). People differ in their degree of delay discounting, the extent to which they forgo larger monetary magnitudes in the future in order to obtain immediate rewards. As in previous work, the immediate reward will be fixed and the magnitude and delay of the larger, later reward will vary from trial to trial. Participants will make 51 choices. The primary outcome will be the subjects discount rate, which will be estimated by fitting a logistic regression that assumes a persons decisions are a stochastic function of the difference in subjective value between the two options.127 Keeping with standard behavioral findings128,129 we will assume that subjective value (SV) is a hyperbolic function of the reward amount (A) and delay (D): SV = A/(1+kD), where k is the participants discount rate. Larger values of k indicate a greater degree of discounting future rewards. A composite measure of impulsivity will be calculated by averaging individual z-scores derived from the SST, Stroop interference score, and k-value. We predict that higher levels of impulsivity indicating poor response inhibition and greater discounting of future rewards (i.e., slower SST, higher Stroop interference score, and higher k-values) will be associated with less weight loss 24 months following bariatric surgery. Psychopathology: Psychopathology measures will be administered via interview or questionnaire at the following time points: baseline and 6, 12, and 24 months after surgery. The tasks are: Structured Clinical Interview for the DSM-5, Research Version (SCID-5-RV)129 is a semistructured interview for making DSM-5 diagnoses for mood, anxiety, eating, substance use, and psychotic disorders. A trained clinician or mental health professional who is familiar with the DSM-5 classification and diagnostic criteria administers the measure, which takes about 2.5 hours. Beck Depression Inventory-II (BDI-II)130: survey used to measure mood. It is the most widely-used measure of depressive symptomatology. Alcohol Use Disorders Identification Test (AUDIT)164: assesses the presence of alcohol use disorders before and after surgery. The Drinker Inventory of Consequences131 is a self-administered 50-item questionnaire designed to measure adverse consequences of alcohol use in five areas: Interpersonal, Physical, Social, Impulsive, and Intrapersonal. Each scale provides a lifetime and past 3-month measure of adverse consequences, and scales can be combined to assess total adverse consequences. The Fagerström Nicotine Tolerance Questionnaire132 is an 8-item, self-report designed to measure physical dependence to nicotine. Urine Drug Screens: collected in temperature sensing cups to ensure valid samples. Urines will be tested for common drugs of abuse (cocaine, opiates, amphetamines, methamphetamine, marijuana). A composite measure of psychopathology will be calculated by averaging individual z-scores derived from the presence/absence of DSM diagnoses, the BDI-II score, and the substance use measures. We predict that higher levels of psychopathology will be associated with less weight loss 24 months following bariatric surgery. Eating Behavior: Eating behavior measures will be administered via interview or questionnaire at the following time points: baseline and 6, 12, and 24 months after surgery. Total administration time is approximately 30 minutes. The tasks are: The Eating Inventory134: 51-item self-report inventory that measures three factors related to eating behavior: 1) cognitive restraint, 2) disinhibition, and 3) hunger. Eating Disorders Examination-Bariatric Surgery Version135: Identical to the widely-used Eating Disorders Examination but also measures eating disturbances specific to bariatric surgery by adding specific questions regarding dumping, plugging, chewing and spitting, and vomiting. (Note. The diagnosis of BED will be established from the SCID interview. The results of the EDE-BSV will be used as a continuous variable in the analyses described below.) Night Eating Questionnaire (NEQ)127: 14-item scale that measures symptoms of night eating and has been used in bariatric populations previously. Yale Food Addictions Scale136: 25-item mixed response scale that is used to identify those who are using high sugar/high fat foods in ways similar to symptoms that are markers of substance use, such as tolerance, withdrawal, and loss of control. A composite measure of disordered eating will be calculated by averaging individual z-scores derived from these measures. We predict that higher levels of disordered eating will be associated with less weight loss 24 months following bariatric surgery. Weight: Weight will be measured with a calibrated digital scale with subjects dressed in light clothing and without shoes. Percent weight loss will be calculated from participants current weight (at each assessment point) as compared to their baseline weight. Participants with higher levels of impulsivity, psychopathology, and disordered eating are predicted to lose less weight at 24 months as compared to those with lower levels. Psychosocial Status: Medical Outcomes Study 36-Item Short Form Survey (SF-36)137: used to measure quality of life Impact of Weight on Quality of Life-Lite (IWQOL-Lite) 138: used to measure quality of life Dietary Intake: ASA-24: public-access, freely available (through the National Cancer Institute), web-based tool to obtain high-quality dietary intake data with minimal bias, making it a preferred tool for studying diet and disease associations.139 These 24-hour food recalls will be conducted at each time point for one weekday and one weekend day. Physical Activity: College Alumnus Survey (commonly known as the Paffenbarger Survey140): calculate self-reported leisure time physical activity kilocaloric expenditure per week. The frame of reference will be the past 6

months. This survey has excellent reliability and validity, including predictive validity for cardiovascular disease outcomes, and compares favorably to 7 day recall. (Note. We acknowledge that objective measures of physical activity have been found to be more reliable in bariatric samples.141 However, as change in physical activity is an outcome of secondary interest, we have elected to use a well-known self-report measure. We hypothesize that changes in quality of life, dietary intake, and physical activity will be associated with changes in weight. Social Support: The Medical Outcomes Study Social Support Survey is a brief, multidimensional, self-administered, social support survey that was developed for patients in the Medical Outcomes Study (MOS), a two-year survey that was developed for patients with chronic conditions. This survey was designed to explore various dimensions of functional social support, including emotional/informational support, tangible support, affectionate support, and positive social interaction. Sherbourne and Stewart (1991) found that the support measures are reliable (all Alphas 0.91), and are fairly stable over time. Selected construct validity hypotheses have been supported. Prevalence and Control of Chronic Diseases: 1) T2D will be identified using hemoglobin A1c (HbA1c) and glucose measurements obtained from fasting blood samples, and will be defined as HbA1c 6.5% and glucose 7.0 mmol/L (126 mg/dL), or use of antidiabetes medication.36 Prevalence will be calculated using number of participants with T2D as the numerator and total number of participants as the denominator. Controlled T2D, among individuals diagnosed with T2D, will be defined as HbA1c 7.0%.36 These labs are drawn as part of standard clinical care and the HbA1c and glucose results will be extracted from the EMR of enrolled participants. Participants will not be asked to have additional blood draws as part of the study. 2) Hypertension: systolic blood pressure (SBP) and diastolic blood pressure (DBP) will be measured using a Dinamap 9300XL monitor.. Using recently updated US guidelines, hypertension will be defined as SBP130 mm Hg, or DBP80 mm Hg, or use of antihypertensive medication.39 Prevalence will be calculated using number of participants with hypertension as the numerator and total number of participants as the denominator. Controlled hypertension, among individuals with hypertension, will be defined as SBP130 mm Hg and DBP80 mm Hg.39 Blood pressure is measured as part of standard clinical care. SBP and DBP will also be extracted from the medical record of enrolled participants from their preoperative testing with the bariatric surgery program as well as their postoperative follow up with the surgical team. Participants will have blood pressure measured as part of the study assessment. This blood pressure reading will be collected using a standardized protocol. Participants will be asked to remain seated for 5 minutes prior to the reading. Blood pressure will then be measured three times in a seated position with one minute rest between readings using the Dinamap 9300XL monitor. Healthcare Utilization: This information will be extracted from electronic medical records (EMRs) for the following services: primary care, hospitalizations, and emergency room visits. Total number of visits and number of visits to each service will be calculated for all-cause, mental health, T2D, and hypertension related, separately. Duration of stay will also be assessed.41,42 Based on previous experience of the research team, over 70% of participants will receive their non-bariatric care in the TU or Penn systems during the study. Therefore, we will be able to obtain utilization records through the EMR. However, to ensure complete data capture, we will also use a standardized and validated method employed in the Action for Health in Diabetes (Look AHEAD) study which assesses health services utilization using interviews at study visits.43 Medication Adherence: Among individuals with T2D and hypertension, medication adherence will be calculated, separately, using EMR data for pharmacy fills. We will use the prescription-based proportion of days covered (PDC) method to calculate adherence during the first and second year following surgery. PDC numerator will be defined as number of days with medication available to take between the date of the first medication fill during each time period (Year 1 and 2, separately) to the date of the last fill within the period, and the denominator will be the number of days between the date of the first and last fills during the period.44 Adherence will be defined as a PDC80%. In anticipation of missing EMR data on pharmacy fills, during the baseline, 6-, 12-, and 24-month study visits, we will administer the K-Wood-4 Medication Adherence Scale, a 4-item self-report questionnaire, to assess adherence and provide a way to validate results obtained from the EMR. Temple Health participants will have the option of completing the above assessments in English or Spanish. Participants whose surgery date is scheduled greater than 90 days after their baseline assessment (due to delays in scheduling surgery) may be asked to return to the clinic to complete a portion of the assessment. Participants will be asked to complete the ASA 24 hour dietary food recall and the impulsivity tasks (described above) within approximately 2-8 weeks prior to surgery in order to ensure that these data are within the appropriate time frame prior to surgery. We anticipate that this portion of this assessment will take approximately one hour to complete. If participants are willing to return to the clinic to complete these two portions of the assessment, they will be compensated $25 for their time.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

Analysis Plan
Analysis will be conducted using Stata 13.0 (Stata Corporation, College Station, TX). After the completion of quality assurance procedures, descriptive statistics will be summarized for all patients by predictor group (dichotomized). Data screening: Prior to performing analyses, standard data screening/ cleaning procedures will be applied. These procedures will: screen the data for data-entry errors; check for outliers; assess the extent and pattern of missing data; create all summary scores needed for analysis; and check that appropriate assumptions of normality are met. In all analyses, the assumptions underlying the application of all the statistical methods that are used will be examined, principally through the use of standardized residuals, influence diagnostics, and graphical displays. Image processing will include image quality assessment procedures that examine global and region of interest (ROI) based raw and processed temporal signal-to-noise ratio, absolute and relative motion, and signal spike count. Potential outliers will be identified in the cumulative sample by examining quality assessment measures and flagging for further investigation subjects greater than two standard deviations from the mean on any one measure (i.e., behavioral performance, image distortion and artifact, general linear model fit). The purpose of this evaluation is to determine whether the time series is likely valid, and, if so, it will remain. Otherwise it will be corrected, if feasible, or removed from the analysis. The final sample will be examined in a similar fashion to determine whether any subjects warrant data cleaning or require exclusion from the final statistical analysis. Analysis of repeated measures: Our four-session within-subject design will generate multiple outcome measures that belong to the Gaussian family, and we will therefore use standard repeated-measures analysis of variance (ANOVA). Imaging outcomes (perfusion and BOLD) will be modeled using standard voxel-based image analysis techniques (described below) that incorporate random effects. Other outcomes (weight loss, ratings) will be modeled using a linear mixed-effects models framework, using using Stata 13.0 (Stata Corporation, College Station, TX). We could use a population averaged approach such as generalized estimating equations. However, the mixed model approach will provide the flexibility to allow for different error variances for different sessions if necessary. Voxel-based image analysis has limited flexibility, particularly when adding multiple covariates and interaction. When needed, summary values (e.g., mean rCBF, mean BOLD% signal change) extracted from ROIs will be modeled in STATAs mixed-models framework. These models can be extended to include additional explanatory variables (e.g., weight change, heart rate, respirations, age). Primary Aim 1 We will take a mixed models approach. The main interest in this study is the Group x Time interaction, where Group will be a between-subjects factor and Time will be a categorical within-subjects factor. This can be interpreted as population averages (GEE fitting method). Hypothesis 1: We will fit a 2 (Group: Dichotomized Baseline Measures, Low, High) x 3 (Time: change from baseline to month 6, 12 and 24) mixed-effects model for change in weight. Hypothesis 2: We will fit a 2 (Group: Dichotomized difference scores, 6 Month minus Baseline, Low, High) x 2 (Time: change from baseline to months 12 and 24) mixed-effects model for change in weight. In addition, the mixed effects models will include adjustments for surgical procedure, gender, and time since surgery. We recognize that the change in weight could also be associated with effects of several pertinent patient characteristics. To this end, we will consider additional covariates (e.g. sociodemographic variables, comorbidities, medication use, tobacco use, and initial weight). For both hypotheses, we will explore the continuous version of our predictor variables, where in place of Group, we use the real values of the predictor. This yields a difference of slopes with respect to predictor value across time points. Secondary Aim 1 We will use confirmatory factor analysis to verify our expected natural groupings of individual measures into composite measures. We will specify 3 factors and use Varimax rotation. We will assemble composite scores for each of our constructs by summing the standardized score values. We will then standardize the composite score and outcome (change in weight at 24 months). We will estimate the partial correlations (direct and indirect) among individual measures, composites, and outcome in a path analysis as suggested by Figure 1 to estimate the fraction of variance in outcome accounted for by each of the constructs. Secondary Aim 2 The outcomes will consist of (continuous) changes in behavior from baseline. We will use correlation to examine the relationship of baseline impulsivity measures to changes at 6, 12 and 24 months. The exception is changes in diet composition. In this analysis, we will use multivariate regression methods,

with a 3 level time (6m, 12m, and 24m) x continuous (change), for the different nutrient categories. Missing data The best approach to handling missing data is not to have any, by establishing procedures that correct missingness as it is happening within sessions, and by robust retention efforts as detailed above. In spite of our best efforts, it is likely that some subjects will not provide complete data, by dropping out of the study, by missing an assessment, or by failing to complete all assessments in a session. We will adopt analysis practices that mitigate the impact of missing data. First, all analyses will be conducted using the intention-to-treat (ITT) principle, in which all available data on all participants are included. This approach minimizes bias if individuals drop out for different reasons. In an obesity treatment study, a participant lost to follow-up may be an informative dropout. As long as the missing at random assumption is not violated, attrition related to observed variables (i.e., informative dropout), is a missing or unbalanced data scenario that can be accommodated by the proposed mixed effects models. Furthermore, sensitivity analyses (e.g. baseline carried forward, as treated analysis, various multiple imputation methods, pattern-mixture models) can be conducted and results can be compared to those found with the mixed models. An additional cause of missing data will be item non-response. In the event of items missing at random on survey measures, missing items will be imputed prior to calculating final scores using conditional means, estimated with an iterated version of Bucks method,142 and implemented using the EM algorithm in conjunction with ordinal logistic regression.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?
No

Data confidentiality

- x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**
- x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**
- x **Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.**
- x **Wherever feasible, identifiers will be removed from study-related information.**

  A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

  A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)
- x **Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.**

  Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality
Code numbers will be assigned to each subject to maximize anonymity when entering and analyzing data. All data collected will be kept in a locked office, in locked file cabinets and archived after completion of the study.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
Yes

Please affirm that not including this sensitive information in the medical record will not adversely affect the provision of medical care.
Yes

Please outline your proposed method for verifying that the sensitive information being collected for this research will not be recorded, or later entered into the electronic medical record. Please provide a list of the tests that will be ordered as sensitive in EPIC, as well as a list of the staff members that will need to have access to the results of these tests.
The psychological interviews, surveys, computer-based testing, and urine drug tests that will be collected by study personnel will not be included in the participants' EPIC charts. These data are not collected by clinical staff.

Subject Privacy
Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following: What protected health information (PHI) will be collected from subjects in this study. Who will have access to that information and why. Who will use or disclose that information. The rights of a research subject to revoke his or her authorization for use of his or her PHI. In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts will be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period. All participants will be assigned a unique identification number. Results from all measures will be entered into a secure password protected database using the individual identification number. A separate secure database houses names and contact information for follow-up. The computing environment is a secure, heterogeneous, networked system of servers, desktops, and printers, all located at the Center for Weight and Eating Disorders. Research coordinators will review patient charts from bariatric clinic schedules to pre-screen potential participants. These potential participants will be contacted at a clinic visit or by phone to assess their interest in participating in the study. Participants will receive questionnaires via secure REDCap link, which will be sent to the email address they provide.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
Other study team members, who may not be key personnel may have access to data. All will be trained in human subjects protection, as well as in the protection of personal health information.

Data Protection*

- x **Name**
- x **Street address, city, county, precinct, zip code, and equivalent geocodes**
- x **All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- x **Telephone and fax number**
- x **Electronic mail addresses**
- x **Social security numbers**
- x **Medical record numbers**
- **Health plan ID numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Device identifiers/serial numbers**
- **Web addresses (URLs)**
- **Internet IP addresses**
- **Biometric identifiers, incl. finger and voice prints**
- **Full face photographic images and any comparable images**
- **Any other unique identifying number, characteristic, or code**
- **None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision

of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
not applicable

Consent

1. Consent Process

Overview
Participants will be recruited from the Bariatric Surgery Programs at the Hospital of the University of Pennsylvania and Presbyterian Medical Center, all part of Penn Medicine. We will enroll participants until a total of 300 adults have completed baseline visits. We anticipate that we will need to consent a larger number of participants in order to meet this enrollment goal. Based on our previous studies of bariatric surgery patients, we expect that approximately 80% of participants will be women and 20% of participants will be ethnic minorities. Dr. Noel Williams, Director of the Bariatric Surgery Program, conducts approximately 300 bariatric surgery operations per year. Additional surgeons in the Bariatric Surgery Program (at the Hospital of the University of Pennsylvania, Presbyterian Medical Center, and Pennsylvania Hospital) operate on approximately 200 patients per year. In order to increase the diversity and size of our sample, participants will also be recruited from the Temple Health Bariatric Surgery Program. The patient flow at Temple Health is similar to that of the Penn Health System (described below). Participants will be approached by the Research team during their pre-operative testing and education process. The study team member who reviews the consent document will emphasize that participation in the study is voluntary and that medical care will not be influenced by the participants decision to participate or not.

Children and Adolescents
not applicable

Adult Subjects Not Competent to Give Consent
Competence to provide informed consent will be assessed informally, as the likely degree of impairment in the population to be studied is minimal.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
No Waiver Requested

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
No

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks

Bariatric surgery poses several significant risks, including: gastric perforation, staple line disruption, disruption of the gastrojejunal anastomosis with a leak, deep vein thrombosis, pulmonary emboli, and death. These risks will be addressed with patients as part of their informed consent for surgery. Participation in the proposed study has no impact on the risks associated with surgery. WE NOTE THAT BARIATRIC SURGERY IS BEING PERFORMED INDEPENDENTLY OF THIS RESEARCH (I.E., SURGERY IS NOT A STUDY PROCEDURE). Patients overall physical health will be monitored by their bariatric surgeon and/or primary care physician. Thus, these professionals will be primarily responsible for monitoring patients health as they lose weight after surgery, including dietary intake and malnutrition, hypotension or hypoglycemia, or risks associated with increased physical activity. If these or other medical issues come to the attention of research study staff during a study visit, the patient will be encouraged to communicate these findings to his or her physician. The psychometric and more objective neurocognitive tests present little risk to participants. Similarly, the structured clinical interviews are believed to present little risk to participants. Finally, there is the potential that individuals connected with the study will see personal health information not relevant to the study. Risks of complications will be reduced by regularly monitoring participants progress. Safety reports will be created by the Research Coordinators and sent to the PIs and Data Safety and Monitoring Board (DSMB). Study staff will make clear that subjects are not obligated to participate in the study and that their answers will be held strictly confidential. Questionnaires will not contain any identifying information, thus, ensuring the confidentiality of subjects responses. Code numbers will be assigned to each subject to maximize anonymity when entering and analyzing data. All data collected will be received and kept in a locked filing cabinet and on a password-protected computer by the Research Coordinators. Subjects will be informed that they can withdraw from the study whenever they wish and that their withdrawal will not affect the medical care they receive.

Potential Study Benefits

Individual subjects may find participation in this study interesting, but will receive no health benefits from participating in this study. Results will provide important information on the changes in weight, psychopathology, disordered eating, and impulsivity associated with bariatric surgery.

Alternatives to Participation (optional)

The alternative is not to participate in the study.

Data and Safety Monitoring

Who will be responsible for monitoring? The Principal Investigators (David Sarwer, PhD; Temple University), in conjunction with Kelly C. Allison (Site-Principal Investigator), the Penn research coordinator, and Temple University Project Director (Jacque Spitzer, MSEd), will be responsible for overseeing and completing the monitoring process. How will monitoring be performed? During the course of the study, safety and data quality monitoring will be performed on an ongoing basis by the research coordinator, data manager, and study investigators. The Research Coordinator will be responsible for assembling the data and producing these reports, as well as assuring that all parties obtain copies of these reports. The PI, Co-Investigators, and Research Coordinator will meet weekly for approximately 60 minutes, where they will review patients safety and progress as they proceed through the study. Results of all assessments will be reviewed to determine whether subjects have experienced any adverse events. Any serious adverse events, although unlikely given the nature of the proposed study, will be reported within 24 hours to the universitys IRB. Weekly meetings will conclude with the identification of any steps that need to be taken to ensure patient safety. Study initiation. The project director, will be responsible for assuring that all staff and participants understand and accept the obligations incurred in undertaking this study in accordance with 21 CFR Parts 312, 511, 812, 813 and any other applicable regulations; the obligation to obtain informed consent in accordance with 21 CFR Part 50; the obligation to obtain IRB review and approval of a clinical investigation before the investigation may be initiated and to ensure continuing review of the study by the IRB in accordance with 21 CFR Part 56; and to keep the sponsor informed of such IRB approval and subsequent IRB actions concerning the study. Ongoing monitoring. Monitoring will be conducted in accordance with the University of Pennsylvania Sponsor-Investigator Standard Operating Procedure. Review of the rate of subject accrual and adherence to inclusion/exclusion criteria will occur monthly during the recruitment phase. A formal report will be created at the end of each recruitment wave of 80 enrolled participants (approximately 25%, 50% and 75% of subject enrollment) to assure that participants meet

eligibility criteria and ethnic diversity goals outlined in the grant proposal. Once participants have completed a baseline assessment, data on compliance to the protocol will be collected by research staff and reviewed by the study investigators, the study biostatistician, and the safety officer (Dr. Anastassia Amaro, Department of Endocrinology and associated faculty at the Center for Weight and Eating Disorders at the Perelman School of Medicine at the University of Pennsylvania). Compliance will be reviewed with the semi-annual DSMP report (described below) and if the safety officer has concerns about whether compliance has reached a level that might inhibit the ability of the study to test its primary hypotheses, he/she will suggest a conference call for study investigators to discuss methods for improving compliance. In addition, the bariatric surgeons will inform the research team of any surgical or medical complications that occurred peri- or post-operatively among surgery patients. The research coordinator will file all meeting agenda and reports in the study regulatory binder. Assessing Adverse Events Definitions Unanticipated Problems Involving Risk to Subjects or Others Any incident, experience, or outcome that meets all of the following criteria: Unexpected in nature, severity, or frequency (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc) Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research) Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm). Adverse Event An adverse event (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality: results in study withdrawal is associated with a serious adverse event is associated with clinical signs or symptoms leads to additional treatment or to further diagnostic tests is considered by the investigator to be of clinical significance Serious Adverse Event Adverse events are classified as serious or non-serious. A serious adverse event is any AE that is: fatal life-threatening requires or prolongs hospital stay (not including expected hospitalizations related to bariatric surgery) results in persistent or significant disability or incapacity a congenital anomaly or birth defect an important medical event Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious. All adverse events that do not meet any of the criteria for serious should be regarded as non-serious adverse events. Adverse Event Reporting Period The study period during which adverse events must be reported is normally defined as the period from the initiation of any study procedures to the end of the study treatment follow-up. For this study, the study treatment follow-up is defined as at the 18month study assessment visit. Preexisting Condition A preexisting condition is one that is present at the start of the study. A preexisting condition should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period. General Physical Examination Findings At screening and baseline visits, any clinically significant abnormality should be recorded as a preexisting condition. At the end of the study, any new clinically significant findings/abnormalities that meet the definition of an adverse event will be recorded and documented as an adverse event. Abnormal Laboratory Values A clinical laboratory abnormality should be documented as an adverse event if any one of the following conditions is met: The laboratory abnormality is not otherwise refuted by a repeat test to confirm the abnormality The abnormality suggests a disease and/or organ toxicity The abnormality is of a degree that requires active management; e.g. change of dose, discontinuation of the drug, more frequent follow-up assessments, further diagnostic investigation, etc. Expected events Over the 24-month duration of the study, a number of medical events may be expected to occur in obese adults, including routine surgeries and procedures, the development of cancer or chronic conditions, new or increased symptoms from a chronic condition, musculoskeletal problems, and motor vehicle or other accidents (e.g., falls). We will record unexpected events which occur as a result of participation in this research study. The events will be reported to the DSMP but not the IRB. Monitoring for Adverse Events (AEs) and Serious Adverse Events SAEs) Surveillance for SAEs and other relevant clinical events that may be associated with study participation will occur at 6, 12, and 24 months. This will be done using an open-ended questionnaire which asks about new symptoms, urgent/unplanned medical care, and hospitalizations. All adverse events will be recorded but only related, unexpected, and serious events will be reported. Monitoring and Reporting: will be conducted in real-time by all study personnel who have direct contact with participants. Participants will also be instructed to contact the study physician, Dr. Williams, should they experience any adverse events that occur due to participation to the research between study visits. Drs. Allison and Sarwer will review all the Adverse and Unexpected Event Case Report Forms. After removing

identifying patient health information, any AE that is related AND unexpected will be reported to the University of Pennsylvania Institutional Review Board within 10 days. Serious adverse events (e.g., unexpected hospitalization see definition above) will be brought to the attention of the Investigators and study physician within 24 hours and reported in a timely fashion as required by the Data and Safety Monitoring Plan (DSMP), the IRB, and the NIH. If the serious adverse event involved a death that is unforeseen (unexpected) and indicates participants or others are at increased risk of harm, it will be reported to the IRB within 24 hours. For all other deaths the investigators will submit a report to the IRB within 3 days. Data, safety and monitoring report. The PIs will provide a summary of the DSMP report to the NIH on an annual basis, as part of the progress report. The DSMP report will include the participants sociodemographic characteristics, expected versus actual recruitment rates, retention rates, any quality assurance or regulatory issues that occurred during the past year, summaries of AEs and SAEs, and any actions or changes with respect to the protocol. The DSMP report to NIH will also include, if applicable, the results of any hypothesis-testing data analysis conducted. External review. To ensure that the investigators employ appropriate data and safety monitoring strategies, we will have two external reviewers to monitor the study. Dale Bond, PhD (assistant professor of psychiatry and human behavior at The Warren Alpert Medical School of Brown University and The Miriam Hospital) will be asked to review participant recruitment, retention, and statistical power. Sharon Herring, M.D. (a physician at Temple University) will be asked to review reports of adverse events in the surgically-treated patients. In each case, reviewers will receive semi-annual summaries of our findings, following enrollment of the first participant. One of these two reports will coincide with the annual DSMP report. Reviewers will provide their evaluation and recommendations during regularly-scheduled telephone conference calls. Evidence of training in human subject research. All research personnel associated with this study will have completed the University of Pennsylvanias Collaborative Institutional Training Initiative (CITI) for patient oriented research, as well as HIPAA Compliance Training. Documentation of this training will be retained in the study regulatory binder.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment

The benefits of this research far surpass the risks. Results will provide important information on weight loss, dietary intake, eating behavior, and physical activity in patients who have undergone bariatric surgery. As noted above, bariatric surgery entails significant risks. Subjects in the proposed study are presenting for surgery of their own volition and are not being randomly assigned to surgical treatment. The risks inherent in bariatric surgery are not affected by participation in the proposed study. The knowledge gained from this study could potentially advance the management of individuals who undergo bariatric surgery.

General Attachments

The following documents are currently attached to this item:

There are no documents attached for this item.